REMARKS

I. Introduction

Receipt is acknowledged of a final office action dated December 30, 2003. In the action, claims 1, 3, 7-9 and 13 were rejected as allegedly anticipated by Goto *et al.* (Blood, 84(6): 1922-1930 (1994)), claims 2, 4 and 6 were rejected as allegedly obvious over Goto, in view of Kang *et al* (U.S. Patent No. 5,656,448), and claim 5 was rejected as allegedly obvious over Goto, in view of Young *et al.* (U.S. Patent No. 6,335,183).

II. Status of the Claims

Claims 1 and 3 were amended to more clearly state the present invention. No new matter has been added. Upon entry of this response, claims 1-9 and 13 will be under examination.

III. Rejection of the Claims Under 35 U.S.C. § 102

Claims 1, 3, 7-9 and 13 were rejected under 35 U.S.C. § 102 as allegedly not novel over Goto *et al.* In the action, the examiner stated that the Goto reference teaches an immunoprecipitation assay that uses an anti-HM1.24 monoclonal antibody reacted with the soluble HM1.24 antigen in a sample and determines the antigen with a molecular weight of 29 to 33 kD. Additionally, the examiner stated that the Goto reference suggests in his assay washing and solubilizing the cells by sonication in a lysis buffer.

A. Goto does not anticipate the presently claimed invention

Applicants respectfully assert that a soluble HM1.24 antigen protein is distinct from a solubilized HM1.24 antigen protein. In the present invention, the soluble HM1.24 antigen protein is an HM1.24 antigen protein comprising an extracellular domain or part thereof, but does not comprise a transmembrane domain (*See* page 7, line 15 to page 9, line 25). Since the antigen protein does not have the transmembrane domain, it is not anchored to the cell surface. The protein is therefore soluble, and without solubilization by a surfactant.

Moreover, the examiner conceded that "Goto et al....differ from the instant invention by failing to teach the soluble HM1.24 antigen protein or the anti-HM1.24 antibody bound to a support." Office action at 3. Thus, the examiner even recognized the distinction between the teachings in Goto and the present invention.

As discussed in the last action, the solubilized HM1.24 antigen protein of Goto not only comprises the extracellular domain, but also has a transmembrane domain. Therefore, the native form of the protein is anchored to the cell surface and is not soluble. But this protein can then be solubilized by a surfactant, for example, which destroys the cell surface and liberates the protein from the cell surface. Since the HM1.24 antigen protein described in Goto comprises both an extracellular domain and a transmembrane domain, it does not anticipate the presently claimed invention. Thus, the soluble antigen protein of the instant invention is not taught in the art and is therefore novel.

Furthermore, Goto describes that the cells containing the HM1.24 antigen protein were washed and solubilized by lysis buffer (PBS containing 5 mg/ml BSA, 0.5% Nonidet P-40), which contains a surfactant (page 1924, col 2, paragraph 3)). Indeed, Nonidet P-40 is a surfactant that destroys or decomposes the cell surface and prior to the addition of Nonidet P-40, the HM1.24 protein of Goto was insoluble.

Additionally, the examiner asserted that "the ability of a protein to become solubilized is an inherent feature of the HM1.24 antigen." Office action at 5. Applicants respectfully assert that solubilizing an HM1.24 antigen that is not normally a soluble protein is different from a soluble HM1.24 antigen. Accordingly, applicants respectfully request that the instant rejection be withdrawn.

IV. Rejection of the Claims Under 35 U.S.C. § 103

Claims 2, 4 and 6 were rejected under 35 U.S.C. § 103 as allegedly obvious over Goto, in view of Kang because it would have been obvious "to have employed a solid support (beads or plates) as taught by Kang et al in the assay methods taught by Goto et al for the convenience of contacting antigen-antibody reactions in a sample, since such solid supports are considered well known and conventional in the immunoassay art." Office action at 4.

Claim 5 was also rejected as allegedly obvious over Goto in view of Young. Specifically, the examiner stated that it would have been obvious "to fuse a protein to the HM1.24 antigen for use in the assay of Goto et al to enhance an immune response for better detection and sensitivity." Office action at 4.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations. See MPEP 2142. As discussed above, Goto does not teach a soluble HM1.24 protein and therefore, the combination of Goto and Kang, or Goto and Young do not teach, either explicitly or inherently, each and every limitation of the claimed invention. Thus, the claimed invention is not obvious in view of the cited art.

CONCLUSION

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and arguments.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date May 28, 2004

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